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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/746,635	11/13/1996	EDWARD R. BURNS	96700/341	7843

7590 04/19/2005

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/746,635	BURNS ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,24,26 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24,26 and 33-38* is/are allowed.

6)☒ Claim(s) *20* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 2/3/05 is acknowledged and has been entered. Claims 20, 24, and 26 have been amended. Claims 25 and 27-32 have been cancelled. Accordingly, claims 20, 24, 26, and 33-38 are pending and are under examination.

Rejections Moot

Claim Rejections - 35 USC § 103

2. The rejections of claims 25 and 27-32 are now moot in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Olsson et al. (Journal of Applied Biochemistry, 5:437-445 (1983)) in view of Cruse et al. (Illustrated Dictionary of Immunology, 1995) for reason of record.

Response to Arguments

4. Applicant's arguments filed 2/3/2005 have been fully considered but they are not persuasive.

A) Applicant argues that Olsson does not teach or suggest that erythrocyte adenylate kinase can be used as a marker for diagnosing erythrocyte hemolysis in vivo in a subject. According to Applicant, Olsson measured the accumulation of total adenylate kinase and hemoglobin in the plasma of stored units of red blood cells in order to evaluate the viability of stored red blood cells.

In response, Olsson specifically showed that adenylate kinase activity is suitable for monitoring lysis of erythrocytic cells, by virtue of its observed direct correlation with hemoglobin concentration. A person of ordinary skill in the art at the time of the instant invention would have appreciated the correlation between hemolysis and erythrocyte adenylate kinase suggested by Olsson et al. as emphasized by the parallel between hemoglobin and adenylate kinase from erythrocytes. Alternatively, Olsson also taught

that adenylate kinase activity is suitable for monitoring lysis of cells regardless of the presence of hemoglobin; hence, making it an independent, separate, and specific marker for hemolysis from hemoglobin (see page 437, first and second full paragraphs).

In response to applicant's argument that the Olsson reference fails to show that adenylate kinase activity provides a diagnosis of hemolysis in vivo, it is noted that such feature upon which applicant relies (in vivo hemolysis) is not recited in the rejected claims. Alternatively, the red blood cells in the blood bag container as taught by Olsson are obtained or collected from a human subject; hence, any release of adenylate kinase, whether the hemolytic phenomenon took place in vivo within the subject before collection, or in vitro in a blood storage container after collection, is a reflection of the measure of hemolysis.

B) Applicant argues that red blood cells contain a number of proteins, in addition to hemoglobin and adenylate kinase, that are released upon lysis of red cells. According to Applicant, while all the proteins released upon lysis of red blood cells can potentially be markers for hemolysis, not all red blood cell proteins are diagnostic for hemolysis in vivo.

In response, Olsson specifically taught that [erythrocyte] adenylate kinase activity is suitable for monitoring lysis of erythrocytic cells, by virtue of its direct correlation with hemoglobin concentration. Alternatively, adenylate kinase activity is also suitable for monitoring lysis of cells regardless of the presence of hemoglobin; hence, it has specificity as a marker for lysis of cells including erythrocytes (see page 437, first and

second full paragraphs). Further, Applicant's argument is not on point because the obviousness rejection based on the teaching of Olsson as set out by Examiner, is not limited to the relationship between hemolysis and hemoglobin alone. Instead, the obviousness rejection based on the teaching of Olsson is on the premise that adenylate kinase is released along with hemoglobin from lysis of erythrocytes or red blood cells, but is also otherwise released upon lysis of other cells, regardless of the presence of hemoglobin such as in the case of non-erythrocytic cells.

Allowable Subject Matter

5. Claims 24, 26, and 33-38 are allowed. Prior art of record does not teach or fairly suggest determining erythrocyte adenylate kinase activity by multiplying percentage erythrocyte adenylate kinase by the total amount of adenylate kinase activity, and using an antibody specific for erythrocyte adenylate kinase to bind erythrocyte adenylate kinase, to determine the presence of at least about 20 U/L erythrocyte adenylate kinase activity, and to thus diagnose erythrocyte hemolysis in a subject.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641